

target nucleic acid sequence, classified in class 435, subclass 91.2;  
and

Group II: Claims 26-34, drawn to a reagent set for use in amplifying a nucleic acid sequence by polymerase chain reaction, classified in class 536, subclass 24.3.

Office action, page 2. Applicants are required to elect a group for examination on the merits. *Id.*, page 5. In response, Applicants elect Group I (claims 10-25), with traverse.

In traversing the restriction requirement, Applicants draw the Office's attention to M.P.E.P. § 803, which requires that there be a serious burden in examining the claims without restriction. In the present case, the Office has not shown that there would be a serious burden to examine these two groups together. Applicants contend that a search for the subject matter of Group I will significantly overlap with the search for the subject matter of Group II. The information relevant to Groups I and II is often found together in the same publications. In other words, publications that disclose methods of identifying heterologous oligonucleotide sequences for use in amplifying a target sequence, often disclose the use of such sequences as reagents in performing the actual amplification. As a search of Group I will overlap with a search of Group II, Applicants contend that there is no undue burden on the Office to examine the groups together. Accordingly, Applicants respectfully request that the Office withdraw the restriction requirement.

In addition to the restriction requirement, the Office requires Applicants to elect "a single nucleic acid species." *Id.*, page 2. The Office notes

Applicants may also elect an unspecified sequence rather than a specifically disclosed sequence. This election corresponds to invention embodiments as instantly claimed which lack specific sequence limitation(s).

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*Id.*, page 3. Accordingly, Applicants elect the Hepatitis C Viral (HCV) genome as the target gene, with traverse. Oligonucleotide sequences used to detect/amplify the Hepatitis C Viral (HCV) genome are described in Examples 1 and 2 (e.g., SEQ ID NOS: 1-9), and recited in claim 12. The Office also requires that Applicants elect a single amplification method from those listed in claim 24. *Id.*, page 3. Applicants elect the polymerase chain reaction as the process of amplifying the target nucleic acid, with traverse. All of the claims read on these elected species.

In traversing the requirement to elect a single nucleic acid sequence, Applicants respectfully submit that the Office has misconstrued the claimed invention. The claims in Group I are directed to a method of identifying heterologous nucleotide sequences, not to any particular target sequence. The claimed method is generic to any target sequence. Consequently, the Office's search of the claimed invention should be properly focused on methods of manipulating nucleic acids, not on a specific gene or oligonucleotide. Such a search does not require that a single nucleic acid be named. Nor does it pose a serious burden to the Office to search the claimed method without electing a single nucleic acid species. Accordingly, Applicants respectfully request that the Office withdraw the election of species requirement. In any event, if the Office finds the elected species are allowable, the search must be expanded to include other allowable species. M.P.E.P. § 803.

With respect to the election of a specific amplification method, Applicants contend that the Office is focusing on differences in the claims that are unlikely to be relevant to a determination of patentability. While there are many different and well-known ways to amplify a target gene, it is not necessary to limit the present claims to

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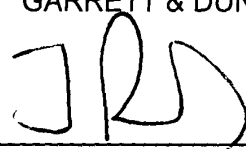
any particular amplification method. In fact, the main claim does not affirmatively recite a step of amplifying a target sequence. That is added in a later dependent claim. Applicants contend that one of skill in the art, after practicing the method of claim 10, can readily select a suitable method to amplify the target gene. Some of these suitable methods are listed in dependent claim 24. But limiting the search of the main independent claim to a specific amplification method, when that claim does not even recite an amplification step, ignores the full scope of the invention and will not aid the Office's search of the invention. Accordingly, Applicants contend that this election of species requirement is in error and provides no value in the examination of the claims. Accordingly, Applicants respectfully request that the Office withdraw the requirement and search the full scope of the claims. Applicants reiterate that if the Office finds the elected species are allowable, the search must be expanded to include other allowable species. M.P.E.P. § 803.

If necessary, please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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